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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte
JULIO C. PALMAZ, STEVEN R.BAILEY
CHRISTOPHER T. BOYLE, and CHRISTOPHER E. BANAS

Appeal 2008-1316
Application 09/707,685
Technology Center 3700

Decided: September 29, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of manufacturing an endoluminal stent. The Examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claims 39-53 and 67-74 stand rejected under 35 U.S.C. § 102(e) as anticipated by Whitcher (Publication No. US 2003/0018381 A1, published January 23, 2003).[1]

As the claims have not been argued separately, and therefore stand or fall together, we select claim 39 as representative of the claimed subject matter for the purpose of deciding all issues raised by this appeal. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 39 is as follows:

39. A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter, and having a plurality of first structural elements defining a longitudinal axis of the stent and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent, comprising the steps of:

a. vacuum depositing a stent-forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate to form a generally tubular, unpatterned crystalline metal film under vacuum deposition process conditions selected to minimize formation of chemical and intra- and intergranular precipitates in the bulk material;

b. defining the plurality of first and second structural elements of the endoluminal stent in the unpatterned metal film; and

c. removing the endoluminal stent from the generally cylindrical substrate.

Thus, claim 39 requires vacuum deposition of a crystalline metal film onto a substrate, under conditions that minimize the formation of chemical and intra- and intergranular precipitates in the bulk material.

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[1] The rejection of claims 39-53 and 67-74 under 35 U.S.C. § 112, first paragraph, has been withdrawn by the Examiner (Ans. 3).

ISSUE

Appellants contend that Whitcher "does not teach, expressly or implicitly, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of . . . [an] as-deposited crystalline film" (App. Br. 8).

The Examiner contends that Appellants' "disclosure points simply to a vacuum deposition process (sputtering and ion-bean evaporation . . .) *as the means for minimizing precipitates and other material properties*" (Ans. 4-5), and Whitcher "dislose[s] use of the same vacuum deposition processes . . . and the use of the same materials used by the applicant . . . and discloses [that] such processes control material properties" (*id.* at 5). Therefore, the Examiner contends, "inherently Whitcher is controlling and minimizing material properties such as granular precipitates" (*id.*).

The sole issue raised by this appeal, then, is whether the evidence of record supports the Examiner's assertion that Whitcher's vacuum deposition process inherently minimizes formation of chemical and intra- and inter-granular precipitates in the bulk material of a deposited crystalline film.

FINDINGS OF FACT

FF1. "The present invention consists generally of an endoluminal stent . . . formed from generally two interconnecting structural regions. First structural regions define circumferential sections of the endoluminal stent . . . arrayed in adjacent, spaced-apart relationship with one another along the longitudinal axis of the endoluminal stent. Second structural regions define longitudinal support sections that interconnect adjacent circumferential

sections . . . and are arrayed about the circumference of the endoluminal stent" (Spec. 4: 3-16).

FF2. "The inventive stent . . . is preferably made of a bulk material having controlled heterogeneities on the luminal surface thereof" (Spec. 10: 22-24). "[H]eterogeneities are controlled by fabricating the bulk material of the stent to have defined grain sizes, chemical and intra and intergranular precipitates" (Spec. 10: 26-28).

FF3. According to the Specification, "physical properties, including . . . elasticity, tensile strength, mechanical properties, hardness, bulk and/or surface grain size, grain composition, and grain boundary size, intra and inter-granular precipitates" are encompassed by the term "material properties" (Spec. 10: 13-16).

FF4. The Specification teaches that "the foregoing properties are achieved by fabricating a stent by the same metal deposition methodologies as are used and standard in the microelectronics and nano-fabrication vacuum coating arts . . . The preferred deposition methodologies include ion-beam assisted evaporative deposition and sputtering techniques" (Spec. 11: 11-15).

FF5. "In ion beam-assisted evaporative deposition it is preferable to employ dual and simultaneous thermal electron beam evaporation with simultaneous ion bombardment of the substrate using an inert gas, such as argon, xenon, nitrogen or neon . . . [which] serves to reduce void content . . . [and] allows the mechanical properties of that deposited material to be similar to the bulk material properties" (Spec. 11: 15-22).

FF6. "Alternate deposition processes which may be employed to form the stent . . . are cathodic arc, laser ablation, and direct ion beam deposition" (Spec. 11: 28-30).

FF7. According to the Specification, "[v]apor deposition of the inventive endoluminal stent . . . significantly reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material" and "the need to control precipitates for mechanical properties is eliminated" (Spec. 14: 19-25).

FF8. There are no working examples in the present Specification, but the Specification indicates that "[m]aterials to make the inventive stents . . . include the following: elemental titanium, . . . nickel, tantalum, zirconium, . . . and alloys thereof, such as zirconium-titanium-tantalum alloys, nitinol, and stainless steel" (Spec. 12: 5-10). In addition, the Specification teaches that "the chamber pressure, the deposition pressure and the partial pressure of the process gases are controlled to optimize deposition of the desired species onto the substrate. As is known in the . . . vacuum coating arts, both the reactive and non-reactive gases are controlled and the inert or non-reactive gaseous species introduced into the deposition chamber are typically argon and nitrogen" (Spec. 12: 11-16). "The deposited material maybe deposited either as a uniform solid film onto the substrate, or patterned" (Spec. 12: 18-19).

FF9. Whitcher teaches that "conventional processes used to produce patterned stents often start with wire, tube or sheet materials" and typical processing steps include winding, welding, heat treating, stamping, cutting, etching, expanding, and/or rolling the material to create the final device

(Whitcher ¶ 3). According to Whitcher, "[m]ost of the manufacturing steps associated with these conventional methods introduce defects into the metallic structure of the formed device" (Whitcher ¶ 4), for example, localized deformation and surface flaws (*id.*).

FF10. According to Whitcher, "[s]ome defects in the formed device may be reduced by techniques, such as annealing, but these techniques often impart other undesirable effects. For instance, annealing often requires high temperature treatment of a metallic device to recrystallize its microstructure to reduce grain size . . . Such a high temperature treatment can often impart physical deformation of the device" (Whitcher ¶ 5).

FF11. Whitcher describes a method of manufacturing medical devices, including radially expandable intraluminal stents with interconnected longitudinal and circumferential structural elements (Whitcher ¶ 45, Figs. 1, 2), "having improved mechanical properties" (Whitcher ¶ 8). According to Whitcher, "the difficulties associated with conventional medical devices and the methods used to form such medical devices" can be overcome "[b]y using vapor deposition techniques" to "accurately and precisely control[ ]" "the composition, thickness, surface roughness, and microstructure" of the medical devices (Whitcher ¶ 28).

FF12. According to Whitcher, "[t]he medical devices formed by the process of . . . [vapor deposition] are tailored to have desired compositions, mechanical properties, and geometries" (Whitcher ¶ 28). Further, a metallic layer "can be formed to have a range of crystalline morphologies, including a monocrystalline or nanocrystalline morphology" using vapor deposition techniques (Whitcher ¶ 48).

FF13. According to Whitcher, "[e]xamples of useful vapor deposition processes . . . include physical vapor deposition processes such as evaporation and sputtering. Direct and assisted ion beam deposition, and chemical vapor deposition are also useful" (Whitcher ¶ 34).

FF14. Whitcher teaches that "[t]he material deposited as the metallic layer [on a mandrel] . . . is any suitable material for use in medical device applications, such as . . . nitinol, stainless steel, titanium, [etc.] . . . The vapor deposition of these materials results in a deposited metallic layer . . . having a fine, equiaxed microstructure which may be precisely established as a function of process parameters. These microstructures in turn affect mechanical properties such as strength and corrosion resistance" (Whitcher ¶ 62). "After release from the mandrel . . . the metallic layer . . . either serves as a stent or as the basis for forming a stent" (Whitcher ¶ 54).

FF15. In Example 1 of Whitcher, an equiaxed, nanocrystalline, "patterned nitinol stent is formed according to the following processing steps" (Whitcher ¶¶ 66, 67):

> A steel wire mandrel measuring about 10 mm in diameter and 30 mm in length is placed in a vacuum chamber . . . Also mounted in the chamber is a nitinol source target comprising about 55.9 wt % nickel and the balance essentially titanium. The chamber is then evacuated to a pressure of less than 10^{-6} torr. Argon is introduced into the chamber at a flow rate . . . producing an operating pressure of about 10 millitorr. A plasma is then generated in the chamber by ion bombardment of the nitinol target, resulting in nitinol deposition onto the wire mandrel. Sputter deposition is continued until the thickness of the deposited nitinol layer is about 0.25 mm, after which the coated mandrel is removed from the chamber.

> The coated mandrel is cut at both ends to a length of about 20 mm. A pattern is formed in the coated mandrel by machining oval-shaped holes through the thickness thereof. The deposited nitinol layer is removed from the mandrel by dissolving the mandrel in hydrochloric acid thus yielding a functional nitinol stent with a fine, equiaxed and nanocrystalline microstructure. . . . A grain size of the nanocrystalline structure is measured to be less than 10 nanometers by this technique.

(Whitcher ¶¶ 66, 67). Examples 2-5 describe additional vapor deposition processes that produce a nitinol layer in nanocrystalline form.

FF16. As an alternative to initial deposition of a crystalline layer, Whitcher describes "[a]nother useful method . . . for forming medical devices . . . [by] crystallization of structures formed with an amorphous morphology" (Whitcher ¶ 41). "The amorphous structure may subsequently be treated or aged under conditions that are well below typical annealing temperatures . . . to form a monocrystalline metallic structure" (*id.*). Whitcher also teaches that another "useful method for forming such [nanocyrstalline] structures is through epitaxy where desired material is deposited [as an amorphous layer] onto a substrate having a crystalline structure, such as an orientated, nanocrystalline structure, and the deposited material forms a crystalline structure similar to that of the substrate" (Whitcher ¶ 43).

DISCUSSION

The Examiner rejected claims 39-53 and 67-74 under 35 U.S.C. § 102(e) as anticipated by Whitcher.

Whitcher describes a method of manufacturing a metallic, radially expandable endoluminal stent with interconnecting longitudinal and circumferential structural elements (FF11). The Examiner acknowledges that "Whitcher does not explicitly recite [minimizing] granular precipitates" (Ans. 5), but contends that Whitcher's method inherently minimizes formation of chemical and intra- and intergranular precipitates in the bulk material, because Whitcher discloses "the same vacuum deposition processes (sputtering, ion beam deposition . . .) and the use of the same materials used by the applicant . . . and discloses such processes control material properties" (*id.*). "Further, Whitcher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties" (*id.*), by "selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which applicant has disclosed to be the method of minimizing precipitates)" (*id.*).

We find no error in the Examiner's conclusion that Whitcher anticipates the claimed invention, based on the evidence of record. The present Specification indicates that the material properties of a crystalline metal film, including "surface grain size, grain composition, and grain boundary size, intra and inter-granular precipitates" (Spec. 10: 15-16; FF3), "are achieved by fabricating a stent by the same metal deposition methodologies as are used and

standard in the microelectronics and nano-fabrication vacuum coating arts" (Spec. 11: 11-13; FF4), preferably "ion-beam assisted evaporative deposition and sputtering techniques" (Spec. 11: 14-15; FF4). No working examples or specific vacuum deposition conditions are described in the Specification (FF8). Rather the Specification merely indicates that the choice of vapor deposition to manufacture metallic stents "significantly reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material" (Spec. 14: 19-21; FF7).

Appellants acknowledge that Whitcher discloses "physical vapor deposition processes of evaporation and sputtering . . . [and] direct and assisted ion beam deposition and chemical vapor deposition" (App. Br. 9), but contend that Whitcher "does not qualify as an enabling prior art reference with regard to . . . [the] pending claims" (App. Br. 16). Appellants argue that Whitcher

> offers no guidance or teaching that any of these processes may be employed to form an as-deposited crystalline film . . . while controlling the deposition process to minimize precipitate formation. The reference merely states the specific conditions selected, *i.e.*, chamber pressure, deposition rate, without any suggestion that those conditions may be controlled in such a manner as to minimize precipitate formation in a crystalline film . . . In fact, none of the Examples found in *Whitcher* contain any statement or suggestion either that 1) the vacuum deposited film is crystalline or 2) precipitate formation has, in fact, been controlled.

(App. Br. 9.)

This argument is not persuasive. First, Whitcher explicitly describes vapor deposition of monocrystalline and nanocrystalline metallic films (FF15). Second, while Whitcher does not specifically mention selecting deposition conditions to minimize precipitate formation, again, the present Specification

merely indicates that the choice of vapor deposition to manufacture metallic stents "significantly reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material" (Spec. 14: 19-21; FF7). Given this teaching in the Specification, the lack of any other disclosure in the Specification regarding deposition conditions (FF8), and the fact that Whitcher describes a method of making stents using the same materials taught by Appellants, and the same vacuum deposition processes taught by Appellants (FF13, 14), to control "the composition, thickness, surface roughness, and microstructure" of the medical devices" and impart "desired compositions, mechanical properties, and geometries" (FF11, 12), we find that the evidence of record supports the Examiner's conclusion that "inherently the precipitates are being controlled" in Whitcher's vacuum deposition method (Ans. 5).

Appellants also argue that Whitcher "teaches depositing a material onto a substrate in its amorphous state and after deposition treating or aging the amorphous structure (as expressly taught in Paragraph 0041) to form either a monocrystalline or nanocrystalline structure" (App. Br. 13). Appellants contend that "[t]his is, without question, different and distinct from the presently claimed invention wherein a film is vacuum deposited as a crystalline layer onto the substrate under conditions which minimize precipitate formation" (App. Br. 13).

We are not persuaded. Paragraph 41 of Whitcher describes "[a]nother useful method" of forming a stent, in which a metallic film is initially deposited as an amorphous layer, and subsequently crystallized (Whitcher ¶ 41, FF16). As discussed above, this is described as an alternative to vapor

deposition of nanocrystalline nitinol films (FF15, 16). Moreover, Whitcher clearly distinguishes between amorphous and crystalline films (FF16).

Similarly, Appellants argue

> [i]n contrast to the conventional nitinol vacuum deposition process described in *Whitcher*, the claimed method eliminates the need for an annealing step. The claimed method achieves this by providing means for vacuum depositing a thin film that is in crystalline form as deposited. As a result, an annealing step is not required, and no precipitates are thereby formed. Thus, Applicants teach a method for minimizing precipitate formation that is distinguished from and not taught by *Whitcher*.

(App. Br. 12.)

Again, this argument is not persuasive. Whitcher explicitly avoids annealing processes by vacuum deposition of an "as deposited" crystalline metallic film which needs no annealing (FF10, 11, 15).

Having considered the respective positions of Appellants and the Examiner, we find that the Examiner has established a prima facie case of anticipation of the claimed invention, which Appellants have not overcome by argument or evidence. We therefore affirm the Examiner's rejection of the claims as anticipated by Whitcher.

SUMMARY

The rejection of claims 39-53 and 67-74 under 35 U.S.C. § 102(e) as anticipated by Whitcher is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

LP

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